

not to obscure previously placed tags or markings.

F. Subpart F—Generator Requirements

The generator's role in tracking medical waste is vital since he is responsible for packaging, labeling, and marking the waste and for initiating the tracking process. The following paragraphs describe major sections of the generator regulations in Subpart F of Part 259.

1. Applicability and General Requirements (Section 259.50)

a. *General.* The rule requires all health care providers or other affected facilities located in the Covered States to determine whether the wastes they generate are regulated medical wastes. The Agency will work with the States, trade associations, and other Federal agencies to inform generators in the Covered States of their new responsibilities under today's rule. Generators who generate mixtures of regulated medical waste and hazardous waste may be subject to today's rule for those mixtures if the waste is not subject to the manifesting requirements of Subtitle C. Mixtures of regulated medical waste and radioactive wastes are subject to today's rule (see Section VII.A of the Preamble).

Under today's rule, vessels (including foreign-flagged ships) must manage any regulated medical waste according to these regulations when at port in a Covered State, and when such waste is to be removed from the vessel for transport and disposal. In situations where a ship is docked at a shore base, the shore base may perform the generator functions, such as maintaining records and initiating the tracking form, if waste is to be sent off-site, provided that the waste is stored at all times in compliance with the on-site storage provisions in § 259.42. In this situation, the ship operator and shore base operator are "co-generators" of the waste, and either may assume generator responsibilities. However, both parties remain liable for compliance.

Wastes managed at the generator's site through incineration, disposal to the sewer, or burial, are not subject to the segregation, packaging, labeling, marking, or tracking requirements. These wastes are subject, however, to storage requirements (§ 259.42) prior to on-site disposal. Additionally, all medical wastes incinerated on-site are subject to a Congressionally-mandated recordkeeping and reporting requirement, discussed below. As discussed above, persons who claim the "treated and destroyed" exemption must also maintain certain records.

b. *Generator exemptions according to quantity.* Generators who will be sending their medical waste off-site must estimate quantities that will be shipped off-site to determine if they may be subject to reduced tracking requirements, as discussed below.

Section 11903(b) allows EPA to establish an exemption from the tracking requirements for generators of small quantities of regulated medical waste based on the quantity generated per calendar month. EPA has determined that some form of exemption from the full tracking requirements is appropriate for generators of less than 50 pounds per calendar month, because the paperwork burden resulting from tracking each shipment individually would overwhelm generators, transporters, treaters and disposers, making the whole tracking system virtually impossible to administer and thus ineffective. This would be especially problematic in a program of short duration that affects persons not formerly subject to similar regulation where Congress clearly envisioned expeditious implementation. Discussions with State officials and health care organizations indicate that under the definition of "regulated medical waste" in today's rule, the universe of generators in the less than 50 pounds per month category would be extremely large (in excess of 100,000). EPA considered an outright exemption under which waste from this category of generators could be disposed of in the normal (e.g., general refuse) solid waste stream. (This would be similar to the "small quantity" hazardous waste generator exemption under 40 CFR 261.5.) EPA rejected this option because some problems have been caused by relatively small quantities of medical waste being improperly managed.

For the reasons discussed above, under today's rule, generators of less than 50 pounds per month of regulated medical waste are responsible for: proper packaging, labeling, and marking of waste; use of transporters who have notified EPA; and use of a log to record when waste is transported off-site (see § 259.50(e)(2)). These generators are not required to complete a tracking form for each shipment, nor are they required to comply with the associated exception reporting requirements. These two exemptions should result in a significant reduction of the paperwork burden for medical waste managers. EPA believes this limited exemption achieves the appropriate balance between the need to ensure that even very small quantities of medical waste are properly managed and the need to develop a program that can be quickly and easily implemented.

Comments are requested on the approach described above.

There are two further considerations related to generators of less than 50 pounds per month. First, wastes disposed on-site (e.g., land-filled or sewer-disposed) are not counted towards the 50 pound limit. Since these wastes would not be subject to the tracking requirements of today's rule, it is not appropriate to change a generator's regulatory status based on the amount of material not sent off-site. (EPA notes that a similar concept is used in the hazardous waste rules at 40 CFR 261.5.) Also, the reader should note that a generator need not count the weight of the packaging materials against the 50 pound per month limit.

Second, the tracking requirements of today's rule apply in full to a generator of less than 50 pounds per month, if he accumulates his waste on-site and ships a package or packages with a total weight of 50 pounds or more at any one time or in any calendar month. The small generator exemption is thus limited to persons who generate less than 50 pounds per month and ship less than 50 pounds at any time. The purpose of the 50 pound shipment rule is to overcome the difficulties in ensuring compliance with the generator's determination that he generates less than 50 pounds per month. Thus, the shipment rule establishes a clear measure for generators and transporters as to when a tracking form must accompany individual shipments of waste.

Under Subpart H of today's rule, transporters who pick up wastes from generators producing less than 50 pounds per month will be responsible for initiating a tracking form for those wastes. However, transporters are allowed to initiate a single tracking form to cover all of the waste present on each truck that is generated by generators of less than 50 pounds per month. A separate tracking document for each generator is not required. Therefore, while the generator is relieved of some of the paperwork burden, his waste still will be responsibly tracked and handled. This is somewhat different from the approach under the hazardous waste regulations. In the hazardous waste regulations, EPA does not regulate waste from generators of less than 100 kilograms (220 pounds) per month (except for acutely hazardous waste; see 40 CFR 261.5). Since the medical waste tracking regulations essentially regulate all listed medical wastes, the Agency determined some flexibility was necessary for managing so many very small shipments, and

developed the approach described above.

c. *Shipments between generators' facilities.* EPA has established special requirements for shipments of regulated medical waste when the waste remains under the generator's direct control (i.e., within an institution or company) (see § 259.51(b)). An institution or company sometimes ships waste from the original generation point (e.g., a location elsewhere in the same city) to a central collection point where waste is consolidated for further shipment or treatment, including incineration. In the Uniform Hazardous Waste Manifest system, when shipments of hazardous waste move "off-site" (i.e., must traverse along, as opposed to across a public road), a manifest is required. For regulated medical waste, EPA believes that tracking of such internal waste movements and use of transporters that have notified EPA is unnecessary, provided certain conditions are met.

As an alternative to the full tracking provisions in today's rule, EPA is allowing a generator to transport his own waste without a tracking form from the point of original generation to a central collection point within the same State (see § 259.51(b)) provided he complies with the packaging, labeling, and marking provisions of Subpart E and the additional reporting requirements of § 259.56 of Subpart F. Generators who elect to use this exemption are required to keep operating logs at each site of original generation and central collection point, containing information similar to that required of generators of less than 50 pounds per month under § 259.50(e)(2).

When transporting the shipment, the generator's representative (probably an employee) signs the first log maintained at the point of original generation; upon delivery to the central collection point, the representative signs the second log maintained at the central collection point. At that time, the waste is once again subject to all of the requirements of Part 259, including Subpart G if the waste is incinerated. EPA believes that since the waste is under the generator's direct control during this transit, and since the transport will typically be short distances, the waste will be properly managed without the need for the tracking form.

This approach is different from that required under the hazardous waste regulations (i.e., each shipment of hazardous waste sent off-site (traversing public roads) must be manifested). Available information indicates that medical waste does not pose the same kinds or degree of hazard posed by hazardous waste, which is why EPA has

not listed medical waste as hazardous waste. Further, EPA anticipates that many medical waste generators, such as research facilities, will want to transport small amounts of medical waste to central locations for further management. Under the Subtitle C program, generators of less than 100 kilograms (220 pounds) per month may ship waste without a manifest. Under today's rules, all generators of regulated medical waste are regulated. Requiring initiation of tracking forms from all of these generators could overwhelm the tracking system and make it difficult to implement, especially given the relatively short duration of the demonstration program.

d. *Transport by generators of less than 50 pounds of regulated medical waste per month.* EPA also has established special requirements for generators of less than 50 pounds per month. In certain circumstances (§ 259.51(a)), these generators may be exempt from the requirement to use transporters who have notified EPA, and from the requirement to use the tracking form. This exemption allows a generator to transport his own regulated medical waste in his personal vehicle to his place of business, a health care facility, or a treatment or disposal facility, without the need to comply with the transporter notification requirements, provided the waste is properly packaged, labeled, and marked. To qualify for this exemption, the generator must have a written agreement with the facility to accept the waste. The purpose of this provision is to ensure that medical professionals (e.g., physicians or veterinarians) providing medical services away from their place of business are allowed to transport the waste back to either: (1) Their place of business for proper transport to a treatment or disposal facility; or (2) directly to a health care, treatment, or disposal facility. EPA has established these conditions because the Agency believes that health care professionals are capable of safely transporting small amounts of regulated medical waste when compliance with the full set of requirements would be impractical.

While EPA's hazardous waste regulations do not make special provisions for this kind of transport, under Section 261.5, EPA does not regulate the transport of such small amounts of hazardous waste (except acutely hazardous waste).

Finally, the reader should note that small individual generators may find it economical to contract as part of a group for waste management services. For example, a number of practitioners in a building, each with their own

practice, could contract with a hauling and disposal company as a group. In this case, medical waste could be picked up from each practice within the building in packaging that would not be adequate for off-site transport (i.e., in plastic bags only) but the transporter would then combine the waste in packages that meet all requirements (e.g., boxes, bins, etc.) before actually removing the waste from the building. In this way, these smaller generators could take advantage of economies available when shipping larger quantities. Generators may also make similar arrangements with their building maintenance companies. In either case, each generator of course remains responsible for complying with the applicable generator requirements.

Also, as described in detail below, today's rule would allow transporters to "remanifest" (i.e., combine many small shipments on one tracking form) shipments from small generators, leading to reduced paperwork. Also, the building management company may act under a contractual agreement and perform the remanifesting or consolidation function on behalf of the transporter.

2. Requirement To Use Transporters Who Have Notified EPA (Section 259.50(f))

Except as discussed below for mail shipments, and above for the special provisions in § 259.51 (a) and (b), generators in a Covered State may offer waste only to a transporter who has notified EPA that he intends to operate in that Covered State as a regulated medical waste transporter. The notification procedure for transporters is discussed in Section V.H. of the Preamble and in § 259.72. The generator is responsible for determining whether a transporter that he plans to use has notified EPA. EPA will provide each State with a list of transporters who have notified EPA in their State. Questions concerning the status of a transporter in any Covered State also may be addressed to the Chief, Waste Characterization Branch, U.S. EPA (OS-332), 401 M St. SW., Washington, DC 20460. The Agency will maintain a master list for each Covered State of all transporters that have notified EPA and have been assigned a medical waste identification number.

As described below, when certain regulated medical waste is shipped by mail, as specified in § 259.51(c), generators need not meet the requirement to use a transporter who has notified EPA if certain conditions are met. In meetings with State representatives, EPA was informed that

services are being offered whereby discarded sharps are being sent by mail to facilities for treatment and disposal. Today's rule allows this practice to continue provided the generator sends the shipment by registered mail with a return receipt requested and the shipping package conforms with all U.S. Postal Service requirements. The exemption contained in today's regulations allows this method of transport for generators of less than 50 pounds of regulated medical waste per month who ship sharps (waste Classes 4 and 7); these generators are not required to complete tracking forms for their shipments of less than 50 pounds. For this reason the exemption is limited to those generators who meet the conditions of § 259.50(e)(2)(i). The return mail receipt serves the dual purpose of substituting for the transporter log and tracking form. The Agency notes that the Postal Service is currently reevaluating its rules for shipping biological materials through the mail. EPA will continue discussions with the Postal Service on whether, and under what conditions, such shipments will continue to be allowed.

3. Acquisition and Use of the Tracking Form (Section 259.52)

The core of the demonstration program, as explained above, is the requirement to track medical wastes from the site of generation to the treatment or disposal facility. Each generator of 50 pounds per calendar month or more, or any generator who initiates a shipment of 50 pounds or more, is responsible for initiating a tracking form according to the directions given in § 259.52 and Appendix I. (Requirements for generators of less than 50 pounds per month are discussed below.) Even if the waste is being sent to a non-Covered State, the generator is required to initiate a tracking form so that he may receive a signed copy, assuring him of the waste's receipt at the destination facility. There must be a sufficient number of copies (at least four (4)) so that the generator, each transporter, and the disposal facility or treatment and destruction facility will each have a copy for its records; furthermore, there must be an additional copy to be returned to the generator. States may require additional copies if they so choose under State regulations.

a. Acquisition of the medical waste tracking form. Today's rule provides for a hierarchy of tracking form use similar to that in the UHWM system. As with the Subtitle C hazardous waste manifest, States may choose to print the Federally-required Medical Waste Tracking Form. The State form must be

identical to the one published today as Part 259, Appendix I. If the State in which regulated medical waste is to be disposed (consignment State) is a Covered State supplying and requiring the use of a State-printed medical waste tracking form, then the generator must use the tracking form of the State of disposal. (The same requirement also applies to those instances where the transporter initiates a tracking form.) If the State in which the regulated medical waste is to be disposed is a Covered State that does not supply or require the use of its tracking form, or the State is non-Covered, then the generator must use the medical waste tracking form of the State of generation if it supplies the form. If neither the generator State nor the consignment (disposal) State supplies the medical waste tracking form, then the generator may have the Federal form (attached in the Appendix I to Part 259) reproduced for its use.

Finally, EPA has established provisions today that require a transporter who will be hauling waste to a Covered State which prints the tracking form to obtain the form and supply it to the generator. (See the note after § 259.52(b)(3), and see § 259.74(a)(2).) EPA does not require this of hazardous waste transporters, but given the large number of small medical waste generators (most of whom have had little or no experience in obtaining manifests), and the need to implement the medical waste tracking program quickly, EPA believes it is necessary to place this responsibility on the transporter.

b. Use of the medical waste tracking form. When initiating the tracking form, the generator, or his authorized representative, must fill in the required information and sign the certification on the tracking form. (A transporter may help the generator fill in the information, but the generator is still responsible for complying with Subparts E and F and ensuring that the information entered on the tracking form is correct.) The certification states that the shipment contents are properly classified, packaged, labeled, and marked in compliance with all applicable State and Federal regulations, and that the generator is aware that civil and criminal penalties exist if he withholds or misrepresents information on the form. (See Appendix I for the instructions for completing the Medical Waste Tracking Form.)

The Generator Certification box of the Medical Waste Tracking Form promulgated today is similar to the UHWM generator certification except that it requires that the signatory be

formally authorized to sign for the facility. As under any tracking program, it is particularly important that the person signing the medical waste tracking form have the training and knowledge necessary to determine that the waste is actually properly packaged, labeled and marked. As a result, the person signing the form should be properly designated by the person in charge of the generator's operation (e.g., in a doctor's office, the doctor) in order to ensure that the tracking of medical waste, which is the cornerstone of the demonstration program, is properly carried out.

Although a formal authorization would generally be provided for any tracking form where the signatory must sign on behalf of the facility, the form promulgated today explicitly requires a written authorization. EPA believes that this requirement is warranted for today's form for several reasons. First, the regulations promulgated today will apply to a large and diverse regulated community which previously has not been regulated by EPA. As a result, it is necessary to describe with greater specificity the steps generators will need to take in order to assure that their wastes are properly managed and tracked. A requirement that authorization be written will also expedite awareness by facility officials of their responsibilities under this new program. Because of the relatively short amount of time prior to the effective date of this program and the desire to have the program operational by this summer, there can be no delay in informing and educating persons responsible for medical waste management to the program requirements. Moreover, the need for greater specificity is also heightened by the short duration of the program because there will be little time to revise and cure any shortcomings in the requirements promulgated today, including the generator certification. For these reasons, EPA is promulgating a more detailed generator certification statement in today's form than that required under the UHWM.

The generator must identify his medical waste as either "treated" or "untreated," and must specify the quantity of each (both number of packages and total weight or volume) in Box 11(a) and (b) of the tracking form. EPA also has provided a space (Box 11(c)) for State regulated medical waste. This may be used when a State regulates medical wastes not covered under the Federal program (e.g., wastes from RCRA Sections 11002 (a) 6 through 9 that EPA chose not to list). The

quantity of State regulated wastes should not be recorded in Boxes 11(a) or 11(b) but should be recorded separately in Box 11(c). Finally, the generator must obtain the signature of the initial transporter and retain a copy of the signed tracking form for his records.

If rail shipments are initiated from the site of generation, the generator is responsible for sending at least one copy of the signed tracking form to each of the following: (1) the first non-rail transporter, if one is used; (2) the destination facility, if the waste is transported solely by rail; and (3) the last rail transporter, if the wastes are to be exported.

These requirements are consistent with the Subtitle C Uniform Hazardous Waste Manifest system for transport by rail. The Agency did not wish to impose a system of document handling that may be disruptive to existing practices. The rationale for establishing such a system was developed in 45 FR 12739, February 26, 1980.

Finally, if the generator's medical waste is subject to the Nuclear Regulatory Commission (NRC) regulations as well as EPA tracking requirements, the information required by the NRC can be placed on the tracking form in the appropriate boxes (e.g., generator's name and address). Information required by NRC but not required by EPA (e.g., radionuclide identity) may be placed in Box 14 (Special Handling Instructions and Additional Information). If the space in Box 14 is not adequate, the generator may attach sheets presenting the NRC-required information. Box 14 also may be used for instructions for handling oversized regulated medical waste.

4. Use of Logs by Generators of Less Than 50 Pounds Per Month (Section 259.54(b))

Generators who generate less than 50 pounds of regulated medical waste per calendar month and do not ship in that calendar month any package(s) greater than 50 pounds must maintain a log that contains information on every shipment of medical waste, if tracking forms are not used. The log, which must be maintained on-site for three (3) years from the date of the most recent entry, must provide the following information and must be signed by the transporter when the waste is picked up: the transporter's name and address; the quantity and category of waste transported; and the date of shipment.

If the waste is transported personally by the generator, the log should be completed to reflect this by having that person (e.g., the generator) or his authorized employee, who transports

the regulated medical waste, sign the log as the transporter. The Agency is not requiring the health care facility or destination facility to sign the generator's log since that would require that the generator carry the log with him each time he transported regulated medical waste to a health care facility or the destination facility. To ensure that such wastes are delivered to the health care facility, a treatment or destruction facility, or the destination facility, and that a record of the transaction is available for inspection or compliance monitoring, the Agency is requiring that the health care or destination facility to which the generator transports the waste maintain a log as required in § 259.83(b).

Some generators may not know the volume of waste they generate until the end of a month. Each generator, however, is responsible for determining his monthly generation and complying with the appropriate requirements (see § 259.50(e), introductory text). Generators who believe they may exceed the 50 pounds per calendar month limit in a given month may find it prudent to use the tracking form as a precaution. Some transporters may, in fact, require the tracking form from all generators.

5. Exports of Regulated Medical Waste (Section 259.53)

Generators (including transporters who initiate tracking forms) exporting regulated medical waste to a foreign country for treatment and destruction or disposal are required to request written confirmation from the accepting facility that the waste was received. In addition to receiving the written confirmation, the generator should also receive a copy of the tracking form from the last domestic (U.S.) transporter as required under § 259.74(e). In order to obtain the written confirmation, the Agency suggests that generators, and transporters who consolidate waste not accompanied by a tracking form, who are shipping regulated medical waste to a foreign destination facility could forward two copies of the tracking form directly to the treatment and destruction or disposal facility. The destination generator should request that the owner or operator of the facility, upon receipt of the waste, sign and return a copy of the tracking form, and in fact may want to include such a clause in any contract with the receiving facility.

The Agency also is requiring transporters who deliver regulated medical waste to a foreign carrier, foreign transfer facility, or foreign destination facility, to send a copy of the tracking form to the generator with the

signature of the accepting transporter, transfer facility, or destination facility. If the accepting transporter or destination facility is not willing to sign the tracking form, the last domestic transporter should indicate this in Box 14 of the tracking form (Special Handling Instructions and Additional Information).

Generators, including transporters who have consolidated or remanifested waste onto a new tracking form (see § 259.76), must file exception reports within 45 days, as required under § 259.55, if they have not received written confirmation of receipt of the regulated medical waste by the destination facility. This requirement also applies in the case of foreign shipments.

The requirement that the generator request written confirmation from the destination facility, coupled with the requirement that the last domestic transporter send a signed copy of the tracking form to the generator upon delivery of the waste to a foreign transporter, transfer facility, or destination facility, provides reasonable assurance that the waste has reached the destination facility.

6. Recordkeeping (Section 259.54)

There are a number of recordkeeping requirements for all generators of medical waste, including generators of less than 50 pounds per month. Generators who are required to use the tracking form must keep a copy of each tracking form for three (3) years from the date of acceptance of the shipment by the transporter. These generators also must keep signed copies of each of the corresponding tracking forms signed by the destination facility for at least three (3) years from the date of acceptance of the shipment by the transporter. As with all other recordkeeping requirements of today's rule, the Agency has determined that such records are necessary for compliance monitoring and for providing any generator-specific data needed to assess the effectiveness of the program and the need for national medical waste regulations. Recordkeeping is of particular importance in this program because the size of the regulated universe makes reporting by generators infeasible. The Agency believes that three years is the appropriate time period for record maintenance under this program for the following reasons: it is the standard used in several of the Covered States and other RCRA programs; and it allows appropriate enforcement actions for program violations incurred during the demonstration program.

All records should be kept on-site so that they are easily accessible for inspection. If, however, recordkeeping operations are normally conducted at another corporate or business location, the generator may keep records there, if they will be readily accessible for inspection purposes.

As described in the next section of this Preamble (see Part 259, Subpart G), generators who incinerate wastes on-site must report the volume and type of waste incinerated. (Information about wastes accepted from off-site sources should also be included in the reports, where applicable.) Finally, generators who claim the § 259.30(c)(2)(iv) exemption for waste that has been treated and destroyed must keep records of the amounts treated in such a manner in order to qualify for the exemption.

7. Exception Reporting (Section 259.55)

For the tracking system to accomplish its purpose, officials must be alerted whenever the tracking "circle" is broken. If the generator who initiated a tracking form does not receive a signed copy of the form from the destination facility (and in the case of foreign shipments, from the last domestic transporter) within 35 days after the waste was accepted by the initial transporter, the generator must contact both the transporter and the destination facility to determine what happened to the waste and the tracking form. If a signed tracking form has not been received within 45 days from the initial date of transport, the generator must submit an exception report to the Regional Administrator and to his State that includes: (a) A legible copy of the tracking form for which the generator did not receive a signed copy; and (b) a letter signed by the generator, detailing his efforts to locate the waste.

A copy of the exception report must be kept in the generator's records for three (3) years.

8. Additional Reporting (Section 259.56)

Through broad authorities granted in Section 11004 of the Act, EPA can require generators to furnish additional reports concerning medical waste generated at their facilities. For example, during an enforcement proceeding, the Agency may require additional information concerning the disposition of certain quantities of waste, including medical wastes not sent off-site (e.g., wastes disposed of on-site in sewers or landfills). Section 259.56 codifies the information gathering authority provided in section 11004 with respect to generators of regulated medical waste. Generators are required

to provide any information available upon request. EPA has codified similar provisions for transporters (§ 259.79) and for owners and operators of destination facilities (§ 259.84).

Also, EPA requests comment concerning the various sources of information and strategies available to gather the requisite information to develop the Reports to Congress, required under Section 11008. In particular, EPA requests comments on means to ascertain quantities of regulated medical wastes discharged to sewers or landfilled on-site. Currently, the regulations do not provide for recordkeeping of these practices.

Additionally, it has been requested that EPA require a one-time report from generators describing the quantities of medical waste in the section 11002(a)(6-10) waste types that are not regulated under the Part 259 requirements. EPA has determined that methods other than a generator report (e.g., a statistical sampling of the various generator types) could be used to obtain the same information, with significantly less burden on the generators. EPA requests comment on the necessity of such a generator report and on other means of obtaining similar information.

G. Subpart G—On-Site Incinerator Requirements

Section 11003(c) of RCRA requires EPA to promulgate recordkeeping and reporting requirements for medical waste generators in Covered States who incinerate regulated medical waste on-site and, thus, do not track such waste under the requirements of the demonstration program. The statute further directs EPA to require these generators to prepare and submit a report summarizing the volumes and types of medical waste incinerated on-site during the first 6-month period following the effective date of these regulatory provisions.

The on-site incinerator reporting requirements in today's regulation satisfy this statutory requirement. EPA has decided to use its broad authority under RCRA Section 11004(a) to require information on the incineration process and the incinerators themselves, in addition to the minimum information required by the Act. Also, EPA is requiring the submittal of two reports. The first report will cover the first six (6) months of the demonstration program, while the second will cover the thirteenth through the eighteenth month of the program. EPA believes the minimum information required by the statute will be more meaningful if it is supplemented by information on the incinerator operations, and if it is

obtained both at the beginning of the demonstration program and after generators and regulators have acquired some experience with the specific requirements of the demonstration program. All of the information being requested will be necessary to satisfy the information requirements of RCRA Section 11008, including the present or potential threat to human health and the environment posed by medical waste incineration, and changes in incineration practices attributable to the demonstration program.

EPA chose not to require a breakdown of incinerator waste feed by waste classes as listed in today's rule for two reasons. First, it is not feasible (and in some cases it is impossible) for generators to segregate their wastes according to the seven waste classes. Furthermore, in some cases, the increased handling that would be necessary to segregate wastes could result in increased risks to health care workers and other handlers of the waste. Additionally, there is little benefit in knowing the composition by waste classes of the incinerator's waste feed. To determine health and environmental effects from incineration, knowledge of the BTU content of the wastes and the plastic and metal content is more useful.

Finally, EPA is requesting the information in terms of weight of medical waste. Although the Act says "volume," EPA presumes Congress simply meant amount. Measurements of actual volume are not reliable in this instance. For example, compaction and other volume reduction processes could render a facility's volume estimate meaningless for estimating quantities of waste incinerated.

1. Recordkeeping (Section 259.61)

Today's rule requires medical waste generators who incinerate medical waste on site to compile an operating log containing information on the amounts of waste incinerated, the frequency of incineration, and the length of the incineration cycle.

EPA also is requiring generators with on-site incinerators to provide information on amounts of waste received from sources outside the facility, in order to assure compliance with the § 259.51(a) exemption and to determine how much regulated medical waste is brought from sources such as private physicians or small group practices. This information will provide a more complete picture of the quantities of regulated medical waste being incinerated.